CHPA
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Producers of Quality Nonprescription Medicines and Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
Formerly Nonprescription Drug Manufacturers Association

Hand Delivery

December 9. 1999

Dockets Management Branch
Food and Drug Administration
Rm. 1-23 (HFA-305)
12420 Parklawn Dr.
Rockville, MD 20857

Re: Over-the-Counter Human Drugs; Labeling Requirements;
Final Rule; Docket Nos. 98N-0037, 96N-0420, 95N-0259, 90P-0201

Dear Sir or Madam:

Enclosed please find five copies of a CHPA Memorandum of FDA Working Group Meeting of November 23, 1999, with attachments, concerning the above-referenced final rule. Pursuant to 21 CFR §§ 10.20. 10.40(g)(7) and 10.65(h), please file the Memorandum and attachments in the administrative docket(s) for this matter. Please provide a date-stamped copy to the messenger for our records. Thank you.

Sincerely yours,

Eve E Bachrach

Eve E. Bachrach
Senior Vice President, General Counsel and Secretary

Attachments: As stated

EEB/s

99 DEC -9 P1:36

98N-0337

C5

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Consumer Healthcare Products Association

Memorandum of FDA Working Group Meeting of November 23, 1999

Re: OTC Label Rule
[Docket Nos. 98N-0337, 96N-0420, 95N-0259, and 90P-0201]

On November 23, 1999, FDA held a Working Group Meeting with the Consumer Healthcare Products Association (CHPA) and the Cosmetic, Toiletry and Fragrance Association (CTFA) to discuss (1) confidentiality in the exemption process and (2) sample exemption requests and mock-ups provided by CHPA. A copy of the FDA's agenda for the meeting is Attachment A.

FDA representatives at the meeting included Dr. Robert DeLap (Director, Office of Drug Evaluation V), Dr. Charles Ganley (Director, Division of OTC Drug Products), David M. Fox (Office of the Chief Counsel), Albert Rothschild (Division of OTC Drug Products), and Gerald Rachanow (Division of OTC Drug Products).

Confidentiality of Exemption Requests. CTFA representatives presented a request for a clear process that assures the protection of confidential and other proprietary information in exemption requests submitted under the OTC label rule. CTFA said the FDA procedure should meet the needs and realities of the marketplace, and be consistent with the requirements of pertinent statutes and case law. A copy of CTFA's October 18, 1999 letter and memorandum submitted in advance of the meeting is Attachment B.

Mr. Fox said that there was no intent in the OTC label rule to override the trade secret act or section 301 (j) of the Federal Food, Drug, and Cosmetic Act (FDC Act). He said FDA intended to respect its obligations to maintain confidential commercial information that is exempt from disclosure under the Freedom of Information Act. He said FDA has done a good job over the years of protecting such company information. He said that the maintenance of a Public Docket for exemption requests was not an end run around the Administrative Procedure Act. He said transparency was the goal of the Public Docket for exemption requests, not rulemaking without notice and comment. He said docketed decisions would not be allowed to be used automatically by other companies. The exemption requests would be handled on a case-by-case basis, and not constitute rulemaking.

The CTFA representatives said that there could be unique issues presented in the context of an exemption request under the rule, which depart from the usual kind of information FDA is accustomed to receiving. For example, unique store displays, special product delivery systems, and even the rationale for the packaging could constitute confidential commercial information that should not be subject to disclosure. More explicit notice to a company of FDA's intent to disclose the information is needed, said CTFA, such as a commitment to notify a specific contact person at a company. CTFA said that the exemption request process would function as a kind of premarket clearance by FDA, so it is especially critical that the information provided by companies be protected. Dr. Ganley asked CTFA to provide more specific suggestions to FDA in writing. CTFA agreed to do so.

Samples of Exemption Requests. CHPA representatives made a presentation requesting general guidance on a number of common types of exemptions from provisions of the final OTC label rule. CHPA sought views from FDA on the general kinds of exemption requests it would consider reasonable. CHPA utilized overhead slides, and had also provided package mock-ups to FDA in advance on November 2, 1999. (CHPA's overhead slides are Attachment C.)

CHPA asked for general guidance on common types of exemption requests to: • omit "Drug Facts (continued)" on successive label panels where space is an issue, and instead use prominent arrows to direct the consumer to the next panel • place the voluntary "Questions and Comments" heading outside of the Drug Facts Box where space is an issue • reduce the typesize of headings and subheadings down to 6 point type while maintaining prominence through boldface or color highlighting • reduce typesize of drug facts information to no less than 4.5 point type, consistent with typesizes allowed for all other FDA-regulated products • omit barlines and hairlines • use the "modified format" without regard to the 60/40 test in the rule, since FDA does not differentiate between the standard and modified format in terms of readability • permit use of voluntary directions and warnings in the Drug Facts Box.

Dr. Charles Ganley responded to the CHPA mock-ups using a series of overhead slides, some with pictures of products and some with narrative text only. (Attachment D contains the narrative text slides.)

In each case but one, Dr. Ganley responded to the CHPA mock-ups by presenting a slide showing a competing marketed product packaged in a larger box, with a larger label, or utilizing trade dress features different from the CHPA mock-up. (The sole exception was the Dr. Scholl's mock-up, which illustrated the case for an exemption to permit a voluntary graphic to be included inside the Drug Facts Box.)

Walgreen's Milk of Magnesia mock-up. The CHPA mock-up used a "modified format" without using the 60/40 test. Dr. Ganley showed an FDA slide of Phillips's Milk of Magnesia, which used the "standard format." He said the two competing products contained the same amount of liquid. He said there were options available to make the Walgreen's MOM meet the standard format: The Walgreen's label could be increased in size and changed in shape to wrap around the sides of the bottle, covering the bottle's side seam, as the Phillips' label does. He said the Walgreen's label could be increased "slightly." He said an extra label could be added to the front of the Walgreen's bottle to include marketing copy, as the Phillips' label does.

Alka-Seltzer Plus Liqui-Gels mock-up. Dr. Ganley said that the Alka-Seltzer box could be increased in size for the label information to fit in accordance with the rule. He showed a slide of the CHPA Triaminicin mock-up, and said that the Universal Product Code (UPC) on the Alka-Seltzer product could be made smaller and moved to the same side location as the UPC on the Triaminicin carton. He showed an FDA slide of Equate Nite Time and said that the company had made the box size larger in two dimensions-length and thickness-to accommodate the FDA label rule. He asked why it is not feasible for other products to do the same thing.

Triaminicin mock-up. Dr. Ganley said the UPC was able to fit on the side of the carton. He said it is therefore not a "thin" box and not properly characterized as a "50/50" box, as argued by CHPA. The modified format should not be used. He said the box should be made larger for the OTC label rule to fit.

Children's Tylenol Cold mock-up. Dr. Ganley showed an FDA slide of Equate children's cold product. He said the two competing products-Tylenol and Equate-had the same ingredients, number of tablets, and size of immediate container bottle. He said the Equate product had a larger outer box than the Tylenol product and that the labeling was more readable on the Equate product. He asked why there should be different size boxes for these similar products.

Oxy 55 mock-ups. Dr. Ganley said the different mock-ups of Oxy 55 jars used different typesizes. He asked why the UPC, expiration date and lot numbers could not appear on the top [cap] or bottom of the jar. He said that the container could be made larger to fit the OTC label rule.

Advil v. Equate ibuprofen. Dr. Ganley showed FDA slides of boxes of brand name Advil ibuprofen and store brand Equate ibuprofen. He said the two competing products contained the same active ingredient and same number of tablets. He said that the box sizes of the two products were different by several millimeters in each dimension. He asked why FDA should change the rule instead of the company changing the dimensions of the box.

Nite Time mock-up. Dr. Ganley showed a slide of the CHPA Nite Time mock-up. He asked why optional graphics [with seals of approval] should appear on the information panel of the label. He said the graphics could be moved to the PDP and that there would then be no need to reduce the typesize in the Drug Facts Box. He showed an FDA slide of Vicks NyQuil with a shrink wrap label, and said that the Nite Time company could use the same "creativity" to shrink wrap its label and to follow the OTC label rule.

Contac. The NDA'd Contac product provided by CHPA placed the "Questions and Comments" statement outside the Drug Facts Box. Dr. Ganley said that allowing this was an FDA "mistake." He said there is room inside the Box for the statement. He said consumers will come to expect to see the "Questions and Comments" state inside the Box and if they do not see it there, they will think there is no such statement on the label. Dr. Ganley said if FDA grants an exemption, then the exemption will become the standard and "chops away at the rule."

Mr. Rachanow said he would like to see what the Contac label would look like if it were redone in column format [based on the November 19, 1999 FDA draft guidance on use of column format].

Dr. Scholl's Clear Away. The CHPA mock-up showed a voluntary graphic in the Drug Facts Box, adjacent to the Directions, illustrating how to apply the product to the foot. This was the only mock-up that Dr. Ganley said would be appropriate for a company to request an exemption from FDA. The request would be for an exemption to permit the voluntary directions

graphic to appear within the Drug Facts Box. Nothing else should change in the Drug Facts Box, however.

Robitussin Cold vs. Equate tussin Dr. Ganley showed slides of these two products and said they had different size boxes. He asked why some companies could make changes to their packages to meet the OTC label rule and other companies could not. He said it is a matter of "fairness to companies and consumers" for FDA to require consistency.

Natural Ice v. Tvlenol roll. Dr. Ganley showed a slide with Natural Ice lip balm attached to a card, and a roll of Tylenol without a card. He said the Natural Ice card contained the labeling as required by the rule, and asked why the Tylenol roll was not mounted on a card.

Making general remarks, Dr. Ganley said "the answer is not to cut into the rule," but that "the package should fit the labeling." He said that the rule clearly says that the modified format can only be used if the label space calculation meets the 60/40 test. He asked how FDA would stop the progression from 60/40 if it made an exception for 50/50 labels. He asked how FDA would define a 50/50 label. He said FDA would consider exemptions on a case-by-case basis. He said FDA does not want exemptions to become the basis for across-the-board general exemptions from the rule.

Dr. Ganley said that if there are companies in the marketplace whose packages fit the OTC label rule, then why should FDA grant an exemption to a company that isn't using creativity to make the package fit the rule. He said that companies are able to change the size of the box or label to fit the OTC label rule. He asked, "if FDA can find good companies in the marketplace who make the rule fit, why should we grant another company an exemption?" Dr. Ganley said that there would be no across-the-board exemptions. He said FDA would look at exemption requests on a case-by-case basis to see what has been done to meet the rule. He said it is not enough for a company to show what will fit on a current label. He said the company will have to change or enlarge the label or package to accommodate the OTC label rule.

Dr. DeLap said that a company can always make the package bigger. He said that the exemption process was intended to be used only in specific circumstances where FDA might agree to very minor deviations from the OTC label rule. He said the intent of the rule was to cover the vast majority of products, and that FDA would not expect to grant exemptions for more than a very small number of products. He said he was uncomfortable with the idea that under the exemption process "everything [required by the rule] would be up for grabs."

Dr. DeLap addressed the argument that the "modified format" should be allowed for products not meeting the 60/40 test, such as 50/50 packages. He said he has seen seals of approval and UPC bar-codes included in the label space calculation, and they should not be.

Dr. DeLap addressed the issue of reduced typesize. He said that in one mock-up 5.8 point type was used for text used instead of the 6 point minimum required by the rule. He said that the difference is 5 percent. He said the label could be made that much bigger to make the 6 point type fit.

Mr. Rachanow said the UPC barcodes sometimes appear on label panels bearing the Drug Facts Box. He asked why the industry does not develop a voluntary standard to place the UPC barcode on the side of the box.

Mr. Rothschild said the size of the labels could be made larger to provide more room for Drug Facts. He said FDA had found labels in the marketplace where changes were made to increase the label size. He asked why other products could not make those changes also. He asked why the Walgreen's MOM label could not be made slightly larger.

Dr. Ganley said that for any exemption request FDA would have to see the efforts put forward by the company to meet the OTC label rule as written, including meeting the standard format.

A copy of a November 29, 1999 press report of the meeting by FDC Reports ("The Tan Sheet") is Attachment E.

Attachment A:	FDA Agenda for November 23, 1999 Working Group Meeting
Attachment B :	CTFA October 18, 1999 Letter and Memorandum to FDA
Attachment C:	CHPA overhead slides for November 23 meeting
Attachment D:	FDA overhead narrative slides for November 23 meeting
Attachment E:	November 29 "Tan Sheet" press report of November 23 meeting

w:OTC rule-N23-99 Memo/EEB
December 6, 1999

OTC Labeling Final Rule Working Group Meeting

Date: November 23, 1999

Time: 10:00 a.m. – 12:00 noon

Location: Parklawn Building, 3rd Floor Conference Rooms D & E

Chairperson: Charles Ganley, M.D.

Topics

- Confidentiality in the exemption process
- Exemption request mock-ups provided by CHPA

Agenda

- Introduction by Chairperson (5 minutes)
- Presentation by Robert Brady and Tom Donegan, Jr. on behalf of CTFA: Confidentiality in the exemption process (15 minutes)
- Questions/Discussion: Confidentiality (10 minutes)
- CHPA presentation of material on exemption mock-ups (30 minutes)
- FDA response and discussion/questions (45 minutes)
- Comments from audience (15 minutes)

ATTACHMENT B

C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

October 18.1999

Charles J. Ganley, M. D.
Director
Division of OTC Drug Products (HFD-560)
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

E. EDWARD KAVANAUGH
PRESIDENT

Dear Dr. Ganley:

I am writing to provide further background on our request for a discussion of the need for adequate protection for confidential business information in exemption requests submitted under FDA's OTC Drug Labeling Regulation. By letter of September 30, 1999, we requested time on the agenda of the November 1, 1999 working group meeting to discuss this exemption procedure. This letter is submitted in response to your request that we provide you with more detailed material on the subjects of discussion two weeks in advance of the meeting.

We anticipate a need for 30 minutes to discuss this issue. Robert P. Brady of the law firm of Hogan & Hartson and I will provide the primary presentation on behalf of CTFA at this meeting. Mr. Brady and I anticipate that our presentation will take approximately 15 minutes and we would request that you allot an additional 15 minutes for discussion. Our focus will be on the need for an expedited procedure for consideration of exemptions and the concern over confidentiality of information and material submitted to the Agency as part of an exemption request. I have attached a summary of issues prepared by CTFA related to the confidentiality concerns for your review prior to the meeting.

We would also appreciate a status report on an earlier request by CTFA for modifications to the regulation to allow continued use of traditional trade dress.

Thank you for your consideration of this material. Please contact me if there are any questions regarding the meeting.

Sincerely,

Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel

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http://www.ctfa.org

OTC Drug Labeling Exemption Process –
Public Availability of information

As you know, CTFA is deeply concerned about the status of confidential commercial information provided to FDA by a company seeking an exemption from the OTC drug labeling rule. Presently, the regulation states that "Decisions on exemptions and deferrals will be maintained in a permanent file in this docket for public review". 21 C.F.R. § 201.66(e). These concerns have been amplified by the FDA letter of August 9 1999 to CTFA that suggests that while certain information may be treated as confidential upon receipt and possibly after a decision is made, some aspects of the information may become public when the agency's decision letter is sent to the manufacturer and that letter is made part of the public docket. CTFA has two over-riding concerns that need both dialogue and clarification.

The first issue relates to what constitutes confidential commercial information which is exempt from disclosure pursuant to the Freedom of Information Act (FOIA). 5 U.S.C. § 552(b)(4). CTFA is concerned that there will be information in these industry requests for exemption, such as business and strategic plans as well as trade dress information and other marketing information which FDA does not routinely receive. FDA employees may not

recognize this material as confidential commercial information, but it is clear that it fully meets the legal standard for such protection.

In a recent FDA pronouncement the agency identified examples of confidential commercial information it deals with as including business sale statistics, customer and supplier lists, research data, profit and loss data and overhead and operating costs. Fed. Reg. 5530, 5535 (January 27, 1995). While FDA recognizes that this list is not exhaustive, nonetheless, it raises our concern that FDA needs to understand how other information, such as that identified above, fully meets the statutory and regulatory definitions of confidential commercial information.

In addition, our members need to know - in advance of submitting such data and information - FDA's legal views regarding the highly sensitive business information required for these exemption requests. Companies then may make an informed judgment as to what to provide to FDA with reasonable assurance that it will remain confidential within FDA files.

The need for clarification is increased by the process for FDA release of information that the agency concludes is not confidential commercial information. FDA's FOIA regulations state that FDA ". . .will make reasonable efforts. . ." to notify the company that submitted the information so that it may object and take other legal steps to ensure the continued confidentiality of its

information. 21 C.F.R. § 20.61(e)(l). This lack of full certainty as to notice of public release by FDA only intensifies the need for clearly understood rules and policies in this regard.

The second issue is how to ensure that such information remains confidential. It is CTFA's strongly held position that any information that meets the definition of confidential commercial information must not be made public by FDA under any circumstances. 5 U.S.C. § 552(b)(4); 21 C.F.R. § 20.61. Indeed, while FDA has discretion to release certain information which is otherwise exempt from such FOIA disclosure, FDA's own substantive and binding regulation makes it clear that FDA shall not release confidential commercial information. 21 C.FR. 20.82(b)(1). In light of the final regulation itself and the correspondence described above which suggests the release of certain confidential commercial information, dialogue *and* clarification on this issue is critical.

October 18, 1999

Consumer Healthcare Products Association

Representing Producers of Quality Nonprescription Medicines and Dietary Supplements

Founded 1881

November 23, 1999 Feedback Meeting on OTC Label Content and Format: Feedback, Exemptions, and Special Packaging

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

William Bradley
Vice President, Technical Affairs

Revised: 1 l-22-99

Overview

- **Introduction**
  - Feedback to Industry's Requests
  - Elements of the Final Rule Suitable for Exemption
  - Manufacturing Capabilities: ETL
  - Parity Across FDA-regulated Consumer Products
  - Modified vs. Standard Formats
- **Exemption Process**
  - Overview
  - Elements of a Feedback Letter
  - Examples of Typical Exemptions That Are Needed
  - Elements of a Feedback Letter: Notification Process
- **Special Packaging**

Introduction:
Feedback to Industry's Requests

- **CHPA's and CTFA's Requests**
  - Use of columns (Draft Guidance dated 11/19/99; received 11/22/99)
  - Light type on a dark background (trade dress)
  - **2-year time extension**

  I. is vital that industry have timely and reasonable feedback on these critical issues.

- **Feedback to Company Inquiries**
  - Consistency is needed!

Introduction:
Elements of the Final Rule Suitable for Exemption

- From September 17th Feedback Meeting Any one element, or a combination of elements, of the Final Rule may be suitable for exemption.
- The omission of one or more elements of the Final Rule is unlikely to be perceived by consumers **as seriously** affecting a "standard look," particularly when those omissions may:
  - Help enhance the consumer friendliness of the label
  - Even help the appearance of a standard look (I.e., help to keep the labeling on 1-2 panels VS. 4 panels).

Introduction
Manufacturing Capabilities: ETL

- **Types of "Extended Text Labeling" (ETL):**
  - Spin Label
  - Accordion Label
  - Book Pages
  - Fold Down Fifth Panel
  - Bubble on a card
  - Fifth Panel

ETL is not an across-the-board easy answer to the problems posed by the Final Rule.

- Factors
  - Cost
  - Reduced line speeds (thicker labels)
  - Lack of data showing:
    - Consumer acceptance
    - Consumer understanding
    - Consumer friendliness
  - Limited supplies
  - Lack of experience with shipment (e.g., effect of heat/moisture on adhesive, type integrity etc.)
  - Liability issues re: damage (removal) on the retail shelf
  - Retailer acceptance of unwrapped ETL
  - Reduction in label space (spin label)
  - Non-standard appearance

Introduction:
Parity Across
FDA-Regulated Consumer Products

- **FDA-regulated Consumer Products**
  - OTC Drugs
  - Cosmetics
  - Foods, including dietary supplements
- **Cosmetics, Foods and Dietary Supplements:**
  - Columns
  - Trade Dress
  - 4.5-Point Type Size for Smaller Packages
- **Why not parity for these elements of label formats across all FDA-regulated consumer products?**

Introduction:
Parity Across
FDA-Regulated Consumer Products

- **Columns**
  - A permitted format element for food nutrition labels *[21CFR101.91(d),(e),(h),(j)]*
  - Permitted for dietary supplement labels *[21CFR 101.36(e)(11)]*
- **Light Type on Dark Background**
  - Permitted for foods and dietary supplements *[21CFR 101.9(d)(1)(i); 101.36(e)(3)(ii)]*
  - Cosmetic ingredient labeling needs only be "prominent and conspicuous" *[21CFR701.3(b)]*

Introduction:
Parity Across
FDA-Regulated Consumer Products

- **Type Size**
  - **4.5-point** type standard for smaller DS packages *[21CFR 101.36(i)]*
    - FDA relied on the CHPA Readability Guidelines as support for this rule *[62Fed. Reg. 49838-9, Sept. 23, 1997]*
  - **4.5-point** type is permitted on smaller food labels *[21CFR 101.9(j)]*
  - **< 6-point** type is permitted on cosmetic ingredient labels *[21CFR701.3]*

Introduction:
Parity Across
FDA-Regulated Consumer Products

- **Type Size**
  - The argument that nutrition labeling or DS labeling is less significant to consumers than OTC labeling is unsupportable.
    - Safety issues are the same: food allergies can be fatal.
  - If **4.5-point** type is **permitted** for food, DS, and cosmetic labeling, then FDA must permit 4.5-point type for OTC labeling.

Introduction:
Parity Across
FDA-Regulated Consumer Products

- **Type Size: FDA review of CHPA information**
  - FDA set the 4.5-point type size for dietary supplements in reliance on the CHPA (then NDMA) voluntary label readability guidelines.
    - *"**FDA** set the minimum type size at 4.5 point in response to the **majority** of the comments, which stated that this minimum is consistent with the **NDMA's** Label Readability Guidelines used for over-the-counter drugs **(Ref.** 4). FDA has received **information from NDMA** that shows that **it** did not set this minimum arbitrarily or subjectively, but that it arrived at this minimum type size based on studies of visual acuity and demographics **(Ref.** 7). FDA has been persuaded by **NDMA's** data..." **[62Fed.Reg. 49830-40, Sept.** 23, **1997]***

Introduction:
Parity Across FDA-Regulated Consumer Products

- **Type Size: Evidence-base . . .**
  - The primary evidence that FDA cites does not support a 6-point minimum type size.
    - Watanabe study showed little difference in readability between 6.7- and 3.3-point type.
    - NCL study supported less than 6-point type.

Introduction:
Parity Across FDA-Regulated Consumer Products

- **Type Size: Summary**
  - The 6-point minimum type size of the Final Rule conflicts with FDA regulations for food, dietary supplements and cosmetics.
  - The "support" cited for the 6-point type minimum in the Proposed and Final Rules is itself minimal at best.
  - Evidence supports 4.5-point type as readable.

Introduction:
Modified and Standard Formats

"201.66(d)(10) If the title. headings. subheadings. and information in paragraphs (c)(1) through (c)(9) of this section, printed in accordance with the specifications in paragraphs (d)(1) through (d)(9) of this section, and any other FDA required information for drug products, and, as appropriate, cosmetic products. other than information required to appear on a principle display panel. requires more than 60 percent of the total surface area available to bear labeling, then the Drug Facts labeling shall be printed in accordance with the specifications set forth in paragraphs (d)(10)(i) through (d)(10)(v) of this section."

- **The Rule does not provide that the Standard Format is more readable than the Modified Format.**
- **The 60:40 calculation is therefore without foundation.**
- **The Modified Format should be able to be used without the 60:40 test.**

Overview

- **Introduction**
  - Feedback to Industry's Requests
  - Elements of the Final Rule Suitable for Exemption
  - Manufacturing Capabilities: ETL
  - Consistency and Fairness Across FDA-regulated Consumer Products
  - Modified vs. Standard Formats
- **Exemption Process**
  - Overview
  - Elements of Feedback
  - Examples of Typical Exemptions That Are Needed
  - Elements of a Feedback Letter: Notification Process
- **Special Packaging**

Exemptions
Overview

- We seek feedback on the general concepts shown by the **SKU's** that CHPA submitted to FDA.
  - **We are not seeking exemptions on the specific SKU's that we submitted on 11/2/99 to FDA.**
  - **We understand that there might be minor corrections needed to the label text in some cases, but these minor issues are not today's focus.**
- We ask for feedback[1] on Modified Format, Voluntary Directions/Warnings **and the** types of general exemptions that might be considered by companies.

[1] **For example: as a Feedback Letter, CPG, Guidance. etc**

[See handout/attachment to overheads.]

Exemptions
Elements of Feedback

A Use of Modified Format without the 60:40 calculation

B Voluntary directions and warnings may be included in the Drug Facts box when complying with the Final Rule or requesting an exemption for formatting elements of the Final Rule.

C Feedback on Use of Common Exemptions

1 Scope: Any one or combination of elements of the Final Rule may be considered for exemption.

2 Exemption requests maintaining a 6-point body text

3 Exemptions requests for a proportionate reduction in type size of the body text below 6-points but no less than 4.5-point type, consistent with food and cosmetic labeling regulations.

[See handout/attachment to overheads.]

Exemptions

Label Mockups

Modified Format & Examples of Typical Exemptions

Modified Format: 50:50 Label & Thin Box

- Walgreen's Milk of Magnesia : Current 50:50 Label
- Walgreen's Milk of Magnesia : Standard Format on 50:50 label with run-off
- Walgreen's Milk of Magnesia: Modified Format fits on 50:50 label
- Triaminicin 12's Blister: Standard Format fits on 4 panels – essentially a 50:50 label
- Triaminicin 12's Blister: Modified Format fits on 2 panels – essentially a 50:50 label

"Drug Facts (continued)" vs. Size-to-Fit

- Excedrin 24's Box: Current label
- Excedrin 24's Box: Modified Format with run-off
- Excedrin 24's Box: Modified Format (6-pt type) without without "Drug Facts (continued)" fits
- Excedrin 24's Box: Modified Format and 5.5-point type and "Drug Facts (continued)" fits

"Questions and Comments" outside of DF Box

- Contact 10's Blister: NDA approved label has "Questions and Comments" outside the Drug Facts

Size-to-Fit

- Oxy 55's: Current label
- Oxy 55's: Standard format with run-off
- Oxy 55's: Modified format with run-off
- Oxy 55's: Stnd. format with 5.7 body text fits
- Oxy 55's: Mod. format with 5.7 body text fits

Voluntary Directions.Warnings in Drug Facts Box

- Clear Away Pads: Current label with voluntary directions (diagram)
- Clear Away Pads: Standard format with voluntary directions (diagram)

Exemptions

Modified Format & Examples of Typical Exemptions.

- **Use of Modified Format Without 60/40 Criterion**
  - 50/50 label (Mock-ups)
    - Milk of Magnesia bottle
  - Thin Carton (Mock-ups)
    - Triaminicin
    - Alka-Seltzer Plus Cold
  - **Rationale**
    - The 60/40 criterion is meaningless for packages having equal front and back labels (50/50) or for thin packages where the side panels are minimal.
    - The modified format provides a more standard look than the standard format, if it will fit on fewer panels.
    - The rule itself does not provide that the standard format is more readable than the modified format, so either should be allowed without a 60/40 numerical criterion.

Exemptions

Modified Format & Examples of Typical Exemptions.

- **Reduction in Type Sizes For Small Run-offs**
  - Proportionate Reduction in Type Sizes
    - Oxy Pads
  - Selective Reductions in Type Sizes
    - Nite Time (bottle)
    - Titles/headers to 6-point type, maintaining body text at 6-point and using highlighting (bold face/color) for titles/headers
  - **Rationale:**
    - For support of use of less than 6-point type. (see previous overheads).
    - Use of a size-to-fit process
    - Note: proportionate reductions in type size of body text seem preferable to selective reductions, since there are no data to support than one part of essential (i.e., required) labeling is less important than another part of essential labeling.

Exemptions

Modified Format & Examples of Typical Exemptions.

- **Omission of "Drug Facts Continued"**
  - Examples:
    - Excedrin 24's (not submitted on November 2nd)
    - Alka-Seltzer Plus Cold
  - **Rationale**:
    - Omission of "Drug Facts Continued" will not affect the "standard look," as the consumer perceives the label, and may help the consumer friendly use of the label by maintaining all elements of the final rule.
    - Arrows, or similarly commonly understood routing icons, can be used to direct the consumer sequentially to different panels.

Exemptions

Modified Format & Examples of Typical Exemptions.

- **"Questions and Comments," Outside the Drug Facts Box**
  - **Examples**
    - Contact Capsules
  - **Rationale:**
    - FDA has approved NDA labeling with the new format, allowing "Questions and Comments" outside the Drug Facts Box.

Exemptions

Modified Format & Examples of Typical Exemptions.

- **Use of Voluntary Directions and Warnings in the Drug Facts Box as part of the 60/40 calculation or other common exemptions**
  - The Problem:
    - Situation: A company needs to incorporate voluntary directions (or warnings) into the Drug Facts Label.
    - Problem: FDA has indicated that the company may not use a Modified Format (vs. the Standard Format), since the Standard Format is a fit for the label if the voluntary information is not placed in the Drug Facts Box.
  - The Solution:
    - All calculations and common exemptions would be undertaken by the company assuming that voluntary directions and warnings are a part of the required information.
    - A exemption would be filed by the company.

Exemptions

Modified* Format & *Examples of Typical Exemptions.

- **Use of Voluntary Directions and Warnings in the Drug Facts Box**
  - Rationale:
    - We recognize that the "Drug Facts Box" is FDA's imprimatur that the information within the Box is FDA approved.
    - Voluntary directions and warnings are not "FDA approved," **but** they are essential to companies from the standpoint of providing adequate directions for specific dosage forms, for example, and for liability reasons.
    - Voluntary directions and warnings are most logically included within the Drug Facts Box, so that the label information is not disjointed.
    - By not allowing all calculations and common exemptions to be undertaken assuming that voluntary directions and warnings are a part of the required information, FDA will create an unfriendly label (e.g., illogical placement of warnings) and dampen company interest in providing useful information, thereby undermining OTC labeling.

Exemptions
Elements of Feedback
Notification Process

- ✓ Elements of Feedback
- ✓ Examples of Typical Exemption that Are Needed
- Notification Process for These Typical Exemptions:
  - A company may notify FDA that it intends to use any one or more of these types of common exemption requests and submit such notification to FDA with appropriate documentation to demonstrate the need for such an exemption(s). The agency has 14 days to object to the company's notification, and provide reasons for its objection(s). If FDA does not provide written objections within 14 days of submission of receipt of a letter for exemption, then the exemption request may be considered approved.

Special Packaging

- FDA needs to provide a flexible approach to small labels (e.g., convenience sizes and travel sizes; other small retail labels) because of the many package configurations.

- Without flexibility on this issue, companies will be faced with unacceptable decisions by FDA, given the what the agency is asking companies to do.

Special Packaging

- **For example, convenience and travel sizes account for l-2 % of the market.**
  - This means that they are still a significant part of the OTC business . . . actually a core business for some companies.
  - This also means that any approach FDA would take in this area would affect a small number of packages relative to the very large number of packages for which the Final Rule is a fit.

Special Packaging

- **Special Packaging**
  - 1-2 dose convenience size
  - Short-term convenience
- **Types of Special Packaging**
  - Bubble on a hang card
  - Tin or plastic of 12's
  - Envelopes
  - Thin cartons
  - 2's foil
  - Rolls, single or blister packed
  - Small bottles
  - Others

Special Packaging

- **Types of approaches**
  - Type size exemption
  - Format exemption
  - Package insert in a tin/plastic, with outer statement directing consumers to read the package insert
  - Dispenser labeling
  - Other

Special Packaging

- **We need additional time on this issue.**
  - The solution to convenience sizes will have a retail trade and manufacture component, since one package type does not fit all class of trade.
  - **Recommendation:** Series of follow-up meetings with FDA.

Conclusion

- **Discussion**
  - Feedback on use of columns and trade dress
  - Common Exemptions
  - Approach to special packaging
  - Feedback on time extension

A 2-year time extension would allow us to develop mutually acceptable solutions to the problematic aspects of the Final Rule.

Consumer Healthcare Products Association

Nov. 23, 1999 Feedback Meeting: Final Rule on OTC Label Content and Format

Framework for Feedback/Guidance/Amendment

A. Use of Modified Format: the Modified Format may be used without the 60% calculation, as shown, for example, for outer containers with a front and back label (e.g., a bottle with no outer carton) and for boxes with small side panels that have limited available space for printing (e.g., a carton for a blister card).

B. Voluntary directions and warnings, which are often important to the proper use of the product, may be included in the Drug Facts box when either complying with the Final Rule or requesting an exemption for formatting elements of the Final Rule.

C. Exemption Process: As part of the exemption process, FDA will consider the size and number of Information Panels that are available for required labeling, the need for space to be used by the retail trade for pricing information, and the use of panels to limit the amount of package manipulation by the consumer, thus making for an easier-to-use and more consumer friendly label. The expectation is that in asking for exemptions companies will use a good faith effort to comply with the intent of the Final Rule.

1. Scope: Any one or more aspects of the Final Rule may be considered in the exemption process.

2. Exemptions requests maintaining a 6-point body text, for example, might include:
   a. Omitting ***"Drug Facts*** (continued)," but placing arrows for purposes of directing attention to the next panel.
   b. Placing the header, "Questions and Comments," outside the Drug Facts box but on another area of the outer package label.
   c. Decreasing type size of titles and headers down to 6-point type, with titles and headers nevertheless maintaining prominence through bold face type and/or color highlighting.
   d. Omitting barlines and hairlines

3. As part of exemptions that might include a reduction in type size of the body text below 6-points, the body text might be reduced to no less than 4.5 point type, consistent with dietary supplement, food, and cosmetic labeling regulations. In this regard, a consistent type size should be used for all body text [1].

4. Notification Process: A company may notify FDA that it intends to use any one or more of these types of common exemption requests and submit such notification to FDA with appropriate documentation to demonstrate the need for such an exemption(s). The agency has 14 days to object to the company's notification, and provide reasons for its objection(s). If FDA does not provide written objections within 14 days of submission of receipt of a letter for exemption, then the exemption request may be considered approved.

[1] FDA indicated at the September 17, 1999 Feedback meeting the possibility that it might consider a selective reduction in type size for required information – e.g., actives, purposes, uses, warnings, and directions might be in 6-point type, while the remainder of the required text is in less than 6-point type. Since all required information is considered essential, there is no basis for distinguishing the relative importance of required information by type size. Hence, we advocate use of a proportional reduction of all body text, where needed.

Walgreen's Milk of Magnesia

- Formatting is different on the modified format example
- UPC code is smaller on the modified format
- Options to meet standard label format
  - wrap around label
  - Slightly increase the size of the label
  - Place the UPC code or other information in another location

Phillip's Milk of Magnesia (FDA)

- Similar construction to the Walgreen's but smaller size (Phillip's has larger size similar to Walgreen's)
- Wrap around label
  - [illegible]
  - Contains required labeling on the wrapped portion
- Has extra label "as always stimulant free"

Alka-Seltzer Pius Ligui-Gels

- Use minimum type size permitted for Drug Facts and Headings
- How much does the box size have to be increased in order for the label to fit.
- Why not same size UPC code as Triaminicin (next example)

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Equate nite time (FDA)

- Two different boxes for the same product, same Brand
  - same active ingredients
  - same number of softgels
- Boxes differ in two dimensions
- Companies are capable of [illegible] the size of the box for a drug product

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UPC

- **Advil 200** mg Coated tablets **(#24) has** a **different** size UPC compared to **Advil** 200 mg Liqui-Gels **(#20)**
  - **both have the same size box**
  - both have the UPC on the end **flap**

Triaminicia

- There is space available on the back and side panel
- Use minimum permitted type size
- Would not characterize this as a thin box **(UPC** fits on tbe side)
- How much does the box size have to be adjusted **in** order for the **label** to fit?

Children's Tylenol Cold vs. Equate children's cold (FDA)

- **Same** active ingredients, number of chewable tablets and **size of** immediate container.
- Different boxes in **all** dimensions
- **are there**

Oxy (55 count)

- Facts headings appear to be different type size
- UPC, Expiration and lot on top or **bottom** of product?
- Smaller UPC
- **How** much does **the** container size **have** to be adjusted in order for the **label** to fit?

Advil vs. Equate Ibuprofen (FDA)

- Same active ingredient
- same # of tablets
- Box size difference by several mm in dimensions

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Nite Time

- Why is there optional graphics on the back panel ?
- Without the graphics, there would be no need to reduce type size

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Vicks NyQuil (FDA)

- Why not shrink wrap a label on the back of immediate container?
  - Vicks NyQuil/DayQuil

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Contac

- Comments or questions should not be moved outside the Drug Facts box
- Move the UPC
- Consumers will come to expect to see "Questions or comments?" in the Drug Facts box

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Dr. Scholl's Clear Away

- Exemption request would be appropriate in this case
- Symbols and pictograms will remain voluntary (I 3271)
  - not a substitute for OTC drug product labeling
  - should not direct attention away from required information

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Robitussin Cold vs. Equate tussin (FDA)

. Same active ingredients and number of softgels
- Different boxes in all dimensions
- Many companies will make adjustments to packages to comply with the final rule, why should a few companies not make an attempt?

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Final Rule: Exemptions

- Document why a particular requirement is applicable, impracticable, or is contrary to public health or safety
- The agency will not routinely grant exemptions or deferrals under 201.66(e) for products that claim to be too small to meet the requirements of this rule.(21 CFR 13254 @ 13268)

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Final Rule: Type Size

- The final de addresses the issues raised regarding the selection of 6 point type size
- Companies who comply with the rule by making adjustments in packaging should should not be penalized.. ..that is, granting exemptions to companies who do not attempt to fit the package to the label
- Is it fair to consumers?

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Type Size

- Why is it acceptable to go to a smaller type size on a smaller package when readability and legibility are major concerns?
- The agency also considers the required OTC drug labeling information essential for the safe and effective use of OTC drug products, irrespective of the size or the shape of the package (13276)

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